APR 2 7 2004

510(k) Summary

HTTP Hypothermia Therapy Ltd.

HTTP System

510(k) Number K 040440

Submitter's Name: **HTTP** Hypothermia Therapy Ltd.
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Trade Name: **HTTP** System (**HTTP** 2001 Controller and **HTTP** "Warm me" Blankets)

Classification Name: System, Thermal Regulation

Classification: The FDA has classified these devices under Class II (product code DWJ) which are reviewed by the Division of Cardiovascular, Respiratory, and Neurological Devices.

Predicate Device: The **HTTP** System is substantially equivalent to the Allon 2001 system (MTRE Advanced Technology Ltd.) cleared under K001546 and K003349, and the Bair Hugger Model 750 (Augustine Medical, Inc.) Cleared under K001149 in terms of intended use, indication for use, technological characteristics, performance data and user interface.

Performance Standards: No performance standards have been established for such devices under sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the **HTTP** System complies with the following voluntary standards IEC 60601-1(1988), including amendments #1(1991), #2(1995), IEC 60601-2-35(1997), IEC 60601-1-2(1993), EN 55011(1998), EN 61000-4-2(1995), EN 61000-4-3(1996) EN 61000-4-4(1995), EN 61000-4-5(1995),

CISPR 16-1(1993), CISPR 16-2(1996), MIL-STD, Method 810e and IEC Standards: 68-2.

Indication for use: The **HTTP** System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the **HTTP** System should be used whenever conditions exist that could cause patients to become cold/hypothermic.

The **HTTP** System is indicated primarily for use in hospital invasive care units, in operating, recovery and emergency rooms, in burn units, and on medical/surgical floors. This system can be used with adult patients

Device Description: The **HTTP 2001** Controller and **HTTP** "Warm me" Blankets ("**HTTP** System") are designed to compensate for body heat loss before, during and after surgery, especially cavity surgery, and to compensate for the decrease in intensity of all internal processes due to narcosis.

The system conducts direct heat to up to 4 blankets. **HTTP** Blankets are available in different shapes and sizes, including a modular kit of 4 blankets, e.g., one for each leg, the Full Chest, Half Chest, Back or Abdomen "Warm me" Blanket. The blankets are modular, pliable, disposable, insulated and isolated.

HTTP System is suitable for all patient sizes. Each blanket is connected to a separate heater. A single blanket uses a single heater. The complete set of blankets applies heat to all sections of the patient's body that are not involved in the surgery.

A computerized feedback loop controls patient core temperature in response to each patient's needs, as prescribed by the physician.

The electrical output from Controller to blankets is only 6V. The system is powered by mains or by batteries.

Safety and Effectiveness: The electrical safety of the **HTTP** system was proven through compliance with the EN60601-1 and EN60601-2-35 recognized standards. The electromagnetic immunity of the system was proven through compliance with the EN60601-1-2. The **HTTP** software and software applications have been verified and validated. The biological safety of the **HTTP** blanket has been assured through Biocompatibility testing. The

effective performance of the **HTTP** System has been established through in vitro and clinical studies.

Substantial Equivalence: Evidence of substantial equivalence has been demonstrated through:

- The **HTTP** intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the **HTTP** are similar to those of its predicate devices. Differences between the devices include electrical heat as heating medium, modular blanket design and some other minor technological differences.
- Heating output values of the **HTTP** System are well within previous cleared values of the predicate devices.
- Safety and performance testing demonstrated significant similarity to the predicate devices.

Therefore, the Company believes that the **HTTP** System is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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HTTP Hypothermia Therapy Ltd.
c/o Ms. Dorith Bar-Adon
Belt Rampe Har Hotzvim
Jerusalem 91236 ISRAEL

Re: K040440
HTTP System (2001 Controller and Warm Me Blankets)
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulatory System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: February 16, 2004
Received: February 20, 2004

Dear Ms. Bar-Adon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K040440

Device Name: HTTP system
[HTTP 2001 Controller with HTTP "Warm me" Blankets]

Indications For Use:

The HTTP system is intended to prevent and treat Hypothermia and provide warmth to cold or shivering patients. In addition, the HTTP system should be used whenever conditions exist that could cause patients to become cold/hypothermic.

The HTTP system is indicated primarily for use in hospital, intensive care units, in operating, recovery and emergency rooms, in burns units and on medical/surgical floors. This system can be used with adults patients.

Prescription Use X (Part 21 CFR 801 Subpart D)	OR	Over-The-Counter Use (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040440